

**Amendments to and Listing of the Claims:**

Please amend claims 19, 28, 32 and 33, without prejudice or disclaimer, cancel claims 29-31, without prejudice or disclaimer, as set forth in the following listing of claims, which will replace all prior versions, and listings, of claims in the application:

1 – 18. (Cancelled)

19. (Currently Amended) A non-human transgenic mammal selected from the group consisting of mice, rats, goats, pigs, sheep and cows, whose genome comprises:

(a) an  $\alpha$ -lactalbumin ( $\alpha$ -LA) promoter; and

(b) a nucleotide sequence ~~like~~ operably linked to the  $\alpha$ -LA promoter, the nucleotide sequence encoding a recombinant polypeptide comprising a bovine  $\alpha$ -S1 casein signal peptide of SEQ ID NO:14, and ~~a recombinant mature human clotting factor VIII (FVIII) polypeptide of a B-domain deleted human clotting factor VIII (FVIII) polypeptide having a recombinant spliced site, Ser741-link to-Leu 1643~~ the amino acid sequence from amino acid residue 18 to amino acid residue 1448 of SEQ ID NO:15,

wherein the non-human transgenic mammal secretes the ~~recombinant~~ B-domain deleted human FVIII polypeptide in milk when the mammal is lactating.

20-22. (Cancelled)

23. (Previously Presented) The non-human transgenic mammal of claim 19, wherein the bovine  $\alpha$ -S1 casein signal peptide is encoded by the DNA sequence of SEQ ID NO: 2.

24. (Previously Presented) The non-human transgenic mammal of claim 19, wherein the recombinant polypeptide comprises the amino acid sequence of SEQ ID NO: 15.

25. (Previously Presented) The non-human transgenic mammal of claim 19, wherein the B-domain deleted human FVIII polypeptide is proteolytically processed intracellularly into a light chain having the A3, C1 and C2 domains and a heavy chain having the A1 and A2 domains, wherein the light chain and heavy chain are operably linked by a junction.

26. (Previously Presented) The non-human transgenic mammal of claim 19, wherein the  $\alpha$ -LA promoter is a 2.0-kb bovine  $\alpha$ -LA promoter.

27. (Previously Presented) The non-human transgenic mammal of claim 19, wherein the transgenic mammal secretes up to 50 mg of the B-domain deleted human FVIII polypeptide per liter of milk when the non-human transgenic mammal is lactating.

28. (Currently Amended) A method for making the non-human transgenic mammal of claim ~~[[1]]~~19, the method comprising:

(a) introducing into an embryo of a non-human mammal a transgene comprising

(i) an  $\alpha$ -lactalbumin ( $\alpha$ -LA) promoter; and

(ii) a nucleotide sequence ~~linked~~ operably linked to the  $\alpha$ -LA promoter, the nucleotide sequence encoding a recombinant polypeptide comprising a bovine  $\alpha$ -S1 casein signal peptide of SEQ ID NO:14, and a ~~recombinant mature human clotting factor VIII (FVIII) polypeptide of a B-domain deleted human clotting factor VIII (FVIII)-polypeptide having a recombinant spliced site, Ser741 link to Leu 1643~~ the amino acid sequence from amino acid residue 18 to amino acid residue 1448 of SEQ ID NO:15,

(b) implanting the embryo into a female of the same species as the embryo; and

(c) permitting the embryo to develop into the non-human transgenic mammal of claim ~~[[1]]~~19.

29-31. (Cancelled)

32. (Currently Amended, Withdrawn) Milk collected from the non-human transgenic mammal of claim 19, wherein the milk comprises the ~~recombinant human FVIII polypeptide B-domain deleted human clotting factor VIII polypeptide.~~

33. (Currently Amended, Withdrawn) Milk collected from the non-human transgenic mammal of claim ~~22-24~~, wherein the milk comprises the ~~recombinant human FVIII polypeptide B-domain deleted human clotting factor VIII polypeptide.~~

34. (Previously Presented, Withdrawn) The milk of claim 32, comprising up to 50 mg of the B-domain deleted human FVIII polypeptide per liter of the milk.

35-36. (Cancelled)

37. (Previously Presented, Withdrawn) The milk of claim 33, comprising up to 50 mg of the B-domain deleted human FVIII polypeptide per liter of the milk.